



State of Wisconsin
Governor Scott Walker

Department of Agriculture, Trade and Consumer Protection

Ben Brancel, Secretary

DATE: October 18, 2013

TO: Board of Agriculture, Trade and Consumer Protection

FROM: Ben Brancel, Secretary *Ben Brancel*
Steve Ingham, Administrator, Division of Food Safety *Steve Ingham*

SUBJECT: Regulation of Dairy Plants, and affecting small business; Rulemaking Scope Statement

PRESENTED BY: Steve Ingham, Division of Food Safety

REQUESTED ACTION:

At the November 13, 2013 Board meeting, the Department of Agriculture, Trade and Consumer Protection (DATCP) will ask the DATCP Board to approve a "scope statement" (copy attached) for potential changes to current DATCP rules related to dairy plants. If adopted, the changes will modernize current dairy plant oversight rules to ensure compliance with the most recent version of the Federal Food and Drug Administration's (FDA's) Pasteurized Milk Ordinance (PMO). The PMO standards apply to Grade "A" dairy plants producing fluid milk and certain milk products, such as cottage cheese, cream, and yogurt, which are made from milk that is produced on Grade "A" farms. Wisconsin's rules enforced in Grade "A" dairy plants must be at least as stringent as, and consistent with, the PMO. ATCP 80 also applies to Grade "B" dairy plants, which make products not covered by the PMO, such as butter, ice cream and cheese. Although ATCP 80 is largely consistent with the PMO, the rule must be revised periodically to maintain that consistency and to adapt to changes in the PMO and new innovations in the dairy industry. For example, the latest version of the PMO contains new requirements related to aseptic processing and packaging of dairy products which are not currently in ATCP 80.

DATCP proposes working with industry to modernize language, definitions and requirements for consistency with the PMO. The department will consider a variety of potential rule changes related to topics such as the recently changed statutory definition of a dairy product, delineation of financial responsibilities for milk contractors and dairy plant operators; equipment and facility standards; evaluation of a plant's water supply; microbiological standards for different dairy products; limits for operating a pasteurizer after a seal has been broken, and variance procedures. As part of the ATCP 80 review, the department will also explore writing provisions that are consistent with impending federal regulations (implemented under the Food Safety Modernization Act) that require food processing plants to conduct a hazard analysis and develop a risk-based system of preventive controls. These federal rules will certainly apply to Grade "B" dairy plants; their applicability to Grade "A" dairy plants is currently in question.

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A scope statement spells out the general purpose and scope of a proposed rule. DATCP may not begin drafting a proposed rule (including a proposal to amend or repeal an existing rule) until the Governor approves a scope statement for that rule as required under s. 227.135(2), Stats. This scope statement was approved by the Governor on October 14, 2013. Wisconsin statutes also require the DATCP Board to approve a scope statement before the department can begin to draft a proposed rule. DATCP is required to publish a draft scope statement in the Wisconsin Administrative Register, and file a copy with the Department of Administration (DOA), at least 10 days before the Board approves the scope statement. DATCP filed the attached scope statement with the Legislative Reference Bureau for publication in the October 31, 2013 issue of the Wisconsin Administrative Register and filed a copy with DOA as required.

STATEMENT OF SCOPE

Department of Agriculture, Trade and Consumer Protection (DATCP)

Rule No.: Ch. ATCP 80, Wis. Adm. Code (Existing)

Relating to: Dairy plants, and affecting small business.

1. Description of the objective of the rule:

The department proposes a comprehensive review and revision of ATCP 80 relating to the food safety oversight of dairy plants in Wisconsin. The objective of this proposed rule is to modernize current dairy plant inspection rules in order to ensure compliance with federal Food and Drug Administration's (FDA) Pasteurized Milk Ordinance (PMO), accommodate advances in manufacturing dairy products, and continue ensuring the safety and quality of Wisconsin dairy products. The department will also determine whether and the extent to which revisions are needed to harmonize Wisconsin regulations with federal risk-based preventive controls regulations implemented under the Food Safety Modernization Act.

2. Description of existing policies relevant to the rule and of new policies proposed to be included in the rule and an analysis of policy alternatives; the history, background and justification for the proposed rule:

Wisconsin has more than 400 licensed dairy plants. Grade A dairy plants produce pasteurized fluid milk and milk products such as cottage cheese, cream and yogurt made using Grade A milk from Grade A dairy farms. Grade A milk and milk products must be processed in accordance with standards in the FDA's PMO and are thereby eligible for interstate commerce. The PMO is a guidance document and ATCP 80 is in substantial compliance with it. Ninety-eight percent of the milk produced in Wisconsin is Grade A. Ch. ATCP 80 (Dairy Plants) is a comprehensive rule designed to address the specific challenges of manufacturing milk and dairy products and ensuring that these products are high-quality and safe to consume. ATCP 80 establishes milk bacteriological and compositional quality standards, sets pasteurization requirements, requires milk testing to measure whether these standards are met, and establishes procedures for testing milk and recording results. ATCP 80 also requires dairy plants to keep records of information needed to monitor the safety of their products, and ensure proper financial reporting. The rule also establishes inspection and enforcement requirements, including a requirement that Grade A plants be periodically audited against federal sanitation compliance standards. Finally, ATCP 80 includes labeling requirements for dairy products not sold for human food or animal feed.

Grade B dairy plants make products not covered under the PMO such as butter, ice cream and cheese. Grade B products may be made from either Grade A or Grade B milk. Grade B milk comes from farms that have less stringent bacteriological requirements and are inspected less frequently.

FDA revises the PMO every two years. The current ATCP 80 rules, although largely in compliance with the PMO, must be revised periodically to maintain the needed consistency with the latest version of the PMO and to adapt to new innovations in the dairy industry. For example, the most recently adopted PMO contains new requirements related to aseptic processing and packaging of dairy products which have not been incorporated in ATCP 80.

The department will consider a variety of potential rule changes which mainly, but not exclusively, involve maintaining consistency with the PMO, and relate to topics such as: the statutory definition of a dairy product; delineation of financial responsibilities for milk contractors and dairy plant operators; equipment and facility standards; evaluation of a plant's water supply; microbiological standards for different products; limits for operating a pasteurizer after a seal has been broken; and variance procedures.

As part of its overall review of Ch. ATCP 80, the department will explore provisions consistent with impending federal regulations (implemented under the Food Safety Modernization Act) that require food processing plants to conduct a hazard analysis and develop a risk-based system of preventive controls. The department may propose rule changes addressing this topic, as needed.

Policy Alternatives. FDA revises the PMO every two years and the department must periodically revise ATCP 80 to ensure substantial compliance with the PMO. If the department does not alter the current rule, the rule may not remain consistent with the PMO which could eventually lead to problems when the FDA audits the Wisconsin dairy inspection program for compliance. A failing regulatory audit score could jeopardize the ability of Wisconsin dairy producers and plants to participate in the Grade "A" program and to maintain Wisconsin's reputation as the Dairy State. Current regulations may not be adequate for addressing emerging food safety issues related to dairy processing.

3. Statutory authority for the rule (including the statutory citation and language): Statutory Authority: ss. 93.07 (1), 97.09 (4), and 97.20 (4), Stats.

93.07 Department duties. It shall be the duty of the department:

(1) **REGULATIONS.** To make and enforce such regulations, not inconsistent with law, as it may deem necessary for the exercise and discharge of all the powers and duties of the department, and to adopt such measures and make such regulations as are necessary and proper for the enforcement by the state of chs. 93 to 100, which regulations shall have the force of law.

97.09 Rules.

(4) The department may, by rule, establish and enforce standards governing the production, processing, packaging, labeling, transportation, storage, handling, display, sale, including retail sale, and distribution of foods that are needed to protect the public from the sale of adulterated or misbranded foods.

97.20 Dairy plants.

(4) **RULE MAKING.** The department may promulgate rules to establish the fees required under sub. (2) (c) to (2) (w) or to govern the operation of dairy plants. The rules may include standards for the safety, wholesomeness and quality of dairy products; the construction, maintenance and sanitary operation of dairy plants; the design, installation, cleaning and maintenance of equipment and utensils; personnel sanitation; storage and handling of milk and fluid milk products; pasteurization and processing procedures; sampling and testing; and reports and record keeping. The rules may also set forth duties of dairy plants to inspect dairy farms, collect and test producer milk samples and make reports to the department."

4. Estimate of the amount of time that state employees will spend to develop the rule and of other resources necessary to develop the rule:

DATCP estimates that it will use approximately 0.20 FTE staff to develop this rule. That includes time required for investigation and analysis, rule drafting, preparing related documents, holding public hearings and communicating with affected stakeholders. DATCP will use existing staff to develop this rule.

5. Description of all entities that may be impacted by the rule:

Dairy plant operators will benefit from increased consistency of Wisconsin regulations with the PMO.

6. Summary and preliminary comparison of any existing or proposed federal regulation that is intended to address the activities to be regulated by the rule:

The proposed rule makes ATCP 80 more consistent with the PMO. Although compliance with the PMO is technically a voluntary effort by state regulatory agencies, Wisconsin is periodically evaluated by the FDA for compliance with the PMO. Failure to pass the FDA audit would jeopardize the state's interstate and international dairy industry.

7. Anticipated economic impact

This rule change is anticipated to have no negative impact, but a positive economic impact for Wisconsin's dairy industry. In many respects, it will make Wisconsin's regulations consistent with practices in other states, including those elsewhere in the Upper Midwest which adopt the latest version of the PMO by reference. The rule will not modify fees or have an economic impact on local governmental units or public utility taxpayers.

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Ben Brancel

Secretary

Department of Agriculture, Trade and Consumer Protection

9-20-13
Date Submitted

